

BISMUTH SUBSALICYLATE- bismuth subsalicylate capsule, gelatin coated
Spirit Pharmaceuticals LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Stomach Relief Softgels

Drug Facts

Active ingredient (in each softgel)

Purpose

Bismuth subsalicylate 262 mgUpset stomach reliever and anti-diarrheal

Uses

relieves

- travelers' diarrhea
- diarrhea
- upset stomach due to overindulgence in food and drink, including: heartburn, indigestion, nausea, gas, belching
- fullness

Warnings

Reye's syndrome:

Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product.

When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Contains salicylate. Do not take if you are

- allergic to salicylates (including aspirin)
- taking other salicylate products

Do not use if you have

- an ulcer
- a bleeding problem
- bloody or black stool

Ask a doctor before use if you have

- fever
- mucus in the stool

Ask a doctor or pharmacist before use if you are

taking any drug for

- anticoagulation (thinning the blood)
- diabetes
- gout
- arthritis

When using this product

- a temporary, but harmless, darkening of the stool and/or tongue may occur

Stop use and ask a doctor if

- symptoms get worse or last more than 2 days
- ringing in the ears or loss of hearing occurs
- diarrhea lasts more than 2 days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- swallow with water, do not chew
- adults and children 12 years and over:
- 2 softgels every ½ hour or 4 softgels every hour as needed for diarrhea
- 2 softgels every ½ hour to 1 hour as needed for overindulgence (upset stomach, heartburn, indigestion, nausea)
- do not exceed 8 doses (16 softgels) in 24 hours
- use until diarrhea stops but not more than 2 days
- children under 12 years: ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Other information

- each softgel contains: salicylate 102 mg
- very low sodium
- do not exceed 25°C

Inactive ingredients

aerosil, beeswax, FD&C Red#33, FD&C Yellow#6, gelatin, glycerin, light liquid paraffin, purified water, soya lecithin, sodium carboxy methyl cellulose, sorbitol solution, titanium dioxide

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL

Stomach relief

Bismuth Subsalicylate 262 mg

Upset Stomach Reliever/Antidiarrheal

Soothing relief for 5 symptoms:

- Heartburn • Indigestion • Upset stomach
- Nausea • Diarrhea

12 Softgels



BISMUTH SUBSALICYLATE

bismuth subsalicylate capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4152
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	262 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	

YELLOW WAX (UNII: 2ZA36H0S2V)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)		
LIGHT MINERAL OIL (UNII: N6K5787QVP)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics			
Color	pink	Score	no score
Shape	OVAL (Oblong shaped)	Size	21mm
Flavor		Imprint Code	262
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4152-1	1 in 1 CARTON	04/29/2021	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	04/29/2021	

Labeler - Spirit Pharmaceuticals LLC (179621011)